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December 2, 2015
VIA ECF

Hon. Renée Marie Bumb, U.S.D.J.
United States District Court for the District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets, Courtroom 3D
Camden, NJ 08101

Re: *AstraZeneca Pharmaceuticals LP, et al. v. Mylan Pharmaceuticals Inc., et al.*, Civil Action No. 15-07009 (RMB)(KMW)

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Dear Judge Bumb:

We, together with O'Melveny & Myers LLP, represent Plaintiffs ("AstraZeneca") in the above-referenced action. Pursuant to Your Honor's Rules and Procedures, we write in response to the November 23, 2015 letter submitted by Defendants Mylan Pharmaceuticals Inc. ("Mylan Pharms"), Mylan Laboratories Limited ("Mylan Labs") and Mylan Inc., (collectively, "Defendants" or "Mylan") about Defendants' proposed motion to stay or consolidate this action in light of an earlier-filed action against Defendants and two other Mylan entities, Agila Specialties, Inc. ("Agila") and Onco Therapies Ltd. ("Onco"), Civ. Action No. 15-06039 (the "Agila Action")[1], to dismiss this action, or, in the alternative, to transfer venue. Defendants, along with Agila and Onco, are part of Mylan global group of companies with the same corporate parent (Mylan Inc.).

Defendants are subject to the jurisdiction of this Court, and this Court is the proper, most judicially-efficient venue. Similar motions to dismiss or transfer by Mylan entities have already been rejected in this District. Mylan's arguments here ignore two sets of dispositive facts. First, Mylan closes its eyes to Defendants' connections to New Jersey. Mylan Pharms and Mylan Inc. consented to jurisdiction in New Jersey by registering to do business here. Moreover, Mylan Pharms, Mylan Labs and Mylan Inc. are subject to specific jurisdiction in New Jersey—the ANDA at issue was filed on Defendants' behalf by a New Jersey corporation, located in New Jersey: Agila (now Mylan Pharms). And, second, Defendants disregard the four ongoing related cases on the same four patents before Your Honor. AstraZeneca filed this case in the most judicially-efficient jurisdiction—New Jersey.

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[1] AstraZeneca agrees it is appropriate to consolidate this action with the Agila Action, in which Mylan continues to participate. The Agila Action, No. 15-cv-06039, has progressed as follows: Defendants produced their ANDA on Oct. 8, 2015; Agila answered and filed counterclaims on Oct. 8, 2015 (D.I. 13); Mylan, Agila and Onco served discovery requests on Dec. 1, 2015.

I. This Action and the Related Cases

This patent infringement action arises out of Defendants' Abbreviated New Drug Application ("ANDA") No. 207640, seeking FDA approval to sell a generic copy of AstraZeneca's FASLODEX® (fulvestrant) intramuscular injection product, a breast cancer treatment, the use of which is covered by AstraZeneca's U.S. Patent Nos. 6,774,122, 7,456,160, 8,329,680, and 8,466,139. Four related cases about infringement of these same four patents by proposed generic copies already are pending in this Court: three consolidated as 14-cv-03547 and No. 15-cv-07889.

In a July 24, 2015 letter Agila, a New Jersey corporation with its principal place of business in Lambertville, NJ, notified AstraZeneca that it had submitted the ANDA ("First Notice Letter"). AstraZeneca filed the action against Agila, appropriately in New Jersey, on August 6, 2015. Given Your Honor's familiarity with the subject matter that case from the three consolidated actions, AstraZeneca requested it be assigned to Your Honor pursuant to L. Civ. R. 11.2.[2] AstraZeneca contacted Agila's counsel, which now represents Defendants as well, suggesting consolidation with the ongoing related cases.

Surprisingly, AstraZeneca received a new notice letter dated September 8, 2015 ("Second Notice Letter"), now identifying Mylan Pharms as the U.S. agent (replacing Agila) and Mylan Labs as the ANDA applicant (replacing Onco) due to "corporate harmonization after acquisition."[3] However, both Onco and Agila apparently still exist—the substitution seemingly for jurisdictional argument purposes.

For caution's sake (given the importance of the 30-month-stay), AstraZeneca filed both this complaint and amended the Agila Action complaint. These note that Mylan Inc. now owns the other entities relevant to this ANDA: Agila (now Mylan Pharms), which prepared and submitted the ANDA on behalf of Onco (now Mylan Labs). On information and belief, Mylan Pharms, Agila, Mylan Labs and Onco conduct business under the direction and on behalf of Mylan Inc.

II. Jurisdiction in New Jersey is Proper

Mylan Pharms, Mylan Labs and Mylan Inc. were involved in the ANDA, based on the Second Notice Letter, and AstraZeneca appropriately sued them in this action. All are subject to personal jurisdiction in New Jersey.[4]

Mylan Inc., the parent corporation of Agila, Mylan Pharms, Mylan Labs and Onco, and **Mylan Pharms** consented to the jurisdiction of this Court upon registering to transact business in New Jersey and in this Judicial District. As they concede, Mylan Pharms and Mylan Inc. continuously maintain a registered office in New Jersey and a registered agent for service in New Jersey.

Defendants argue that registering to do business is not enough to find consent to jurisdiction in New Jersey—however, three New Jersey judges in the past year alone have found the opposite, with regard to these same two Mylan entities:

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[2] AstraZeneca requested the fourth case, No. 15-cv-07889, filed November 3, 2015, involving the same subject matter, be assigned to Your Honor for the same reason.

[3] Defendants' letter's gibes of "jurisdictional gamesmanship" and "the confused situation caused by Plaintiffs" are both ironic, given their actions, and empty.

[4] Should the Court entertain Defendants' proposed motion to dismiss, which it should not, AstraZeneca respectfully requests jurisdictional discovery.

- The Court "need not belabor Mylan's arguments, because it cannot be genuinely disputed that consent, whether by registration or otherwise, remains a valid basis for personal jurisdiction following *International Shoe* and *Daimler* . . . the Court finds ample support to conclude that Mylan Inc.'s and Mylan Pharma's compliance with the relevant registration statute amounted to consent to personal jurisdiction." *Otsuka Pharm. Co. v. Mylan Inc.*, No. 14-4508, 2015 WL 1305764, at *9, 11 (D.N.J. Mar. 23, 2015) (Simandle, C.J.).
- The Court denied Mylan Pharms' motion to dismiss based on "prior decisions of this Court" on jurisdiction by consent, "decisions that involved Mylan in nearly an identical posture." *Boehringer Ingelheim Pharma GmbH & Co. KG, et al. v. Teva Pharmaceuticals USA, Inc., et al.*, No. 14-7811, at *2 (D.N.J. July 16, 2015) (Cooper, J.) (citing *Otsuka*).
- The Court "adopted the careful analysis of *Otsuka*" finding that "[b]ecause Defendants have registered with the state to do business in New Jersey, and have conducted a substantial amount of business here, it follows that they have consented to personal jurisdiction in this district." *Janssen Prods., L.P., et al. v. Mylan Pharms. Inc., et al.*, No. 14-4550, at *2 (D.N.J. July 8, 2015) (Wall, J.).

Defendants' only acknowledgement of this binding authority is that their brief "will explain."

Mylan Labs owns the ANDA. The ANDA and Paragraph IV Certification were filed by Agila from its offices in New Jersey, on behalf of Onco, with Agila as Onco's U.S. agent, in New Jersey. The cause of action arose in New Jersey and jurisdiction in New Jersey over Mylan Labs, which stepped into Onco's shoes, is appropriate. *See, e.g., Acorda Therapeutics, Inc. v. Mylan Pharm. Inc.*, 78 F. Supp. 3d 572, 593 (D. Del. Jan. 14, 2015) (considering the actions related to ANDA in forum state). Indeed Agila (now Mylan Pharms), the entity that filed the ANDA, conceded jurisdiction in New Jersey by answering the amended complaint, consenting to jurisdiction and filing counterclaims in the Agila Action.

III. Venue in New Jersey is Most Efficient

Four other litigations involving the same patents are currently pending before this Court and this Court has extensive knowledge of the issues, after a scientific tutorial and claim construction. On this basis alone, Defendants are unable to meet their burden of establishing the need to transfer to a court with no connection to the preparation and submission of the ANDA and no familiarity with the subject matter of the ANDA. *See Celgene Corp. v. Abrika Pharm., Inc.*, No. 06-5818, 2007 WL 1456156, at *4-5 (D.N.J. May 17, 2007). For at least the reasons explained above, Defendants are subject to the jurisdiction of this Court, and this Court is the proper venue.

Thank you for your consideration.

Respectfully submitted,

s/ John E. Flaherty

John E. Flaherty

cc: Counsel of Record (via ECF)